



LSI TR-477-21A

## MAMMALIAN TOXICOLOGY TESTING: PROBLEM DEFINITION STUDY

#### **EQUIPMENT PLAN (U)**

by R. A. Wynveen, R. V. Alban and G. E. Schiefer

March, 1981

Supported by

U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND Fort Detrick, Frederick, Maryland 21701

Contract DAMD17-81-C-1013

Life Systems, Jnc. Cleveland, OH 44122



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REPORT DOCUMENTATION PAGE	READ INSTRUCTIONS BEFORE COMPLETING FORM
2. GOVT ACCESSION NO.  ADA/12 897	3. RECIPIENT'S CATALOG NUMBER
4. TITLE (and Subtitio) MAMMALIAN TOXICOLOGY TESTING: PROBLEM DEFINITION STUDY, EQUIPMENT PLAN	5. TYPE OF REPORT & PERIOD COVERED Supporting Document 15 December 1980-5 April 1981
	6. PERFORMING ORG. REPORT NUMBER LSI TR-477-21A
7. AUTHOR(a)	8. CONTRACT OR GRANT NUMBER(*)
R. A. Wynveen, R. V. Alban, G. E. Schiefer	DAMD17-81-C-1013
9. PERFORMING ORGANIZATION NAME AND ADDRESS	10. PROGRAM ELEMENT, PROJECT, TASK AREA & WORK UNIT NUMBERS
LIFE SYSTEMS, INC. 24755 Highpoint Road Cleveland, OH 44122	62777A.3E162777A878.CC.208
11. CONTROLLING OFFICE NAME AND ADDRESS US Army Medical Research and Development Command	12. REPORT DATE March, 1981
Fort Detrick Frederick, MD 21701	13. NUMBER OF PAGES 56
14. MONITORING AGENCY NAME & ADDRESS(If different from Controlling Office)	15. SECURITY CLASS. (of this report) UNCLASSIFIED
	15a. DECLASSIFICATION/DOWNGRADING SCHEDULE

#### 16. DISTRIBUTION STATEMENT (of this Report)

Approved for Public Release; Distribution Unlimited

17. DISTRIBUTION STATEMENT (of the obstract entered in Block 20, if different from Report)



This report is one of 12 supporting documents to the final reports cited on the reverse side.

19. KEY WORDS (Continue on reverse side if necessary and identity by block number)

Mammalian Toxicology Testing, Mammalian Toxicology, Toxicology, Mammalian,

Mammalian Toxicology Facility, Toxicology Facility, Toxicology Testing

Equipment, Toxicology Support Services

Plans for the identification, acquiring and installation of the scientific and nonscientific equipment required of an Applied Mammalian Toxicology/Research Facility are summarized in this report. The equipment needs were subdivided into 63 different modules reflecting some portion of a Mammalian Toxicology Facility. The needs included debugging through continuing routine testing operations for ten years. Three phases were identified; the time prior to turning over the Facility to the operational team, the first five years of operational testing, and the second five years of operational testing.

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#### 18. continued-

#### Report Subtitle

Life Systems, Inc. Report Number

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Final Reports--

Part 1. Comparative Analysis Report Part 2. Facility Installation Report Part 3. Impact of Future Changes Report LSI-TR-477-2 LSI-TR-477-3 LSI-TR-477-4

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#### FOREWORD

Reports for this Contract, DAMD17-81-C-1013, consist of three major final reports and twelve supporting documents. The Contract title, MAMMALIAN TOXICO-LOGY TESTING: PROBLEM DEFINITION STUDY, is the main title for all the reports. Individual reports are subtitled and referenced with Life Systems, Inc. report numbers as detailed below. Please note that the Life Systems report numbers in test references are shortened. In the Defense Technical Information Center (DTIC) data base the reports are identified by the complete report numbers (i.e., LSI-TR-477-XXX) and complete numbers must be used for retrieval.

Report Subtitle	Life Systems, Inc. Report Number
Final Reports	
Part 1. Comparative Analysis Report	LSI-TR-477-2
Part 2. Facility Installation Report	LSI-TR-477-3
Part 3. Impact of Future Changes Report	LSI-TR-477-4
Supporting Documents	
Technology Changes Impact on Testing Requirements	LSI-TR-477-14
Quality Assurance Plan	LSI-TR-477-17A
Capability Modules	LSI-TR-477-19B
Technical Plan	LSI-TR-477-20A
Equipment Plan	LSI-TR-477-21A
Personnel Plan	LSI-TR-477-23A
Inhalation Chambers and Supporting Equipment Survey	LSI-TR-477-26A
Equipment List for Modules	LSI-TR-477-28B
AMTR Protocol/Pricing Report	LSI-TR-477-29A
Global Army Toxicology Requirements	LSI-TR-477-31A
Comparison Toxicology Test Costs	LSI-TR-477-36A
Annual Testing Capacity	LSI-TR-477-38A

#### SUMMARY

Identifying, acquiring and installing all the scientific and nonscientific equipment that the AMTR Facility will require is a complex undertaking. Although it is only one aspect of the creation of the Facility, it must mesh well with all the other aspects of Facility planning if optimum end results are to be achieved.

The Equipment Plan is further complicated by the fact that the Facility may be located in a building not specifically designed for that purpose. This means that existing equipment must be considered; that built-in equipment there may have to be moved; that door and corridor widths, ceiling heights and floor and elevator loading limits must be accommodated; that utilities must be moved or provided for; etc. A detailed equipment plan is clearly essential if the AMTR Facility is to be suitably equipped by the proper time and at minimal cost.

Nearly 30 experts in toxicological research and testing participated in developing the plan and in determining the equipment for the AMTR modules. They worked within a framework of policies, assumptions and guidelines such as the following:

- US-manufactured, off-the-shelf equipment will be specified whenever possible.
- Medium-quality equipment will be the norm.
- Everything else being equal, movable equipment will be specified rather than built-in.
- A single model and manufacturer will be specified uniformly for each item used in multiples in the Facility whenever possible, to simplify operation and maintenance.
- Redundancy will be provided if necessary to assure that a major testing investment is not jeopardized.
- Maximum flexibility will be a goal, to be achieved by using movable equipment, quick disconnects, multipurpose equipment, cross-training, external support service, etc.
- Excess government property will be used so long as quality of research or testing is not compromised.
- Equipment with a life expectancy of at least 10 years will be procured if it is available at competitive life-cycle costs.

The Equipment Plan was based, in part, on input from other tasks such as Requirements (Task 2), Technical (Task 3), Facility (Task 5), and Quality Assurance (Task 6). In turn, the results of Task 4 were used as inputs to the Resources Plan (Task 8), the Personnel Plan (Task 7), the Facility Plan (Task 5), and the Technical Plan (Task 3).

A schedule was developed for the four major steps of the Equipment Plan (identification, acquisition, installation, and debugging/startup) which takes into account long lead time equipment and facility renovation requirements. Twenty-three key milestones were incorporated into the schedule.

#### Equipment Identification

Sixty three equipment modules to be needed by the AMTR Facility were identified by the Task team, and an itemized list of equipment (and its cost) was prepared for each of the modules. In 1981 currency, the total equipment cost was estimated to be approximately \$25.8 million. This includes the cost of acquisition (initial and replacement items), installation, debugging, and maintenance for 10 years, but not equipment-related operating costs. It assumes that all of the equipment must be purchased and maintained. There will be appreciable reduction in equipment cost if external support services, existing equipment at LAIR and excess Government equipment are utilized.

The team performed a detailed study of inhalation chambers in connection with the identification subtask because chambers will require special design and represent a critical portion of the Facility's total equipment requirements. They contacted 16 of the nation's best inhalation toxicological research and testing facilities and obtained detailed input from six manufacturers of inhalation chambers. Among the many conclusions arising out of this study were these:

- Typical delivery is six months (no design time included).
- Large orders should be divided among several manufacturers so as to reduce delivery time.
- Special chamber systems will need to be designed to meet special Army requirements such as short-term, intermittent, high-level exposures. Interactive computer control appears to be the best approach to meet part of these requirements.
- Nonchamber inhalation exposure methods (e.g., using special exposure helmets) have been developed and are useful for primate exposures.

#### Equipment Acquisition

Equipment for the AMTR Facility can be obtained from several sources:

- Existing items
- Excess equipment from other government facilities (to be secured through the Defense Property Disposal Office, the Defense Logisitics Service Center, and the GSA Property Disposal Office).
- New off-the-shelf items.
- Special items built to AMTR Facility specifications.

New equipment will be acquired through competitive bids pursuant to Government procurement regulations or from the GSA schedule.

#### Equipment Installation

The Equipment Plan and its schedule provide for the key installation-related factors such as:

• Installing built-in equipment during renovation.

- Providing utilities where needed or locating equipment where utilities are available.
- Moving existing equipment with due regard for facility compatibility (e.g., considering corridors, doorways, elevators, weight and height limits, etc.)
- Assembling oversize built-in equipment at its installation location.
- Bringing samples or test materials to the equipment rather than moving equipment to the sample/material location.

The team developed a detailed list of large equipment items that will be installed in the AMTR Facility, including item dimensions.

#### Support Services

The use of external support services was studied carefully because of its potential impact on the Facility's efficiency, capacity and cost. Serious consideration must be given to using external support services if they will avoid the purchase, operation and maintenance of expensive, underutilized equipment. The team developed guidelines for determining which option should be used, depending on what end result is desired.

An example analysis was performed for analytical chemistry support by contacting 12 laboratories in the area for detailed information. It was decided that performers should be limited to the Bay area for reasons of sample delivery and preservation, turnaround time, and shipment costs and time. The study determined that numerous analytical chemistry services in the Bay area can provide routine support and that several are capable of more sophisicated efforts.

#### **FOREWORD**

This report was prepared by Life Systems, Inc. (LSI) under Task 4 of U.S. Army Contract DAMD1781C1013. The effort was completed under the overall direction of Dr. Richard A. Wynveen, Principal Investigator. Mr. Greg Schiefer served as the Task Manager. The final report was prepared and assembled by Mr. Schiefer, Mr. Richard Alban and Dr. Roy H. Reuter. Mr. Earl L. Linaburg of LSI also provided assistance to the plan from the perspective of an individual responsible for purchasing and maintenance.

Col. Alfred Allen served as the Contract Officer's Technical Representative for the Letterman Army Institute of Research (LAIR). Technical assistance on identifying equipment was provided by SRI International, University of California (UC)-Davis, Midwest Research Institute (MRI) and Brookhaven National Laboratory.

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#### LIST OF ACRONYMS

ADP	Automated Data Processing
AMTR	Applied Mammalian Toxicology Research
CBD	Commerce Business Daily
DA	Department of Army
DLSC	Defense Logistics Service Center
DOD	Department of Defense
DPDO	Defense Property Disposal Office
FSN	Federal Stock Number
GLP	Good Laboratory Practices
GOCO	Government Owned Contractor Operated
GSA	General Services Administration
ICAIR	Interdisciplinary Consulting and Information Research
LAIR	Letterman Army Institute of Research
LSI	Life Systems, Inc.
MRI	Midwest Research Institute
NTP	National Toxicology Program
QA	Quality Assurance
UC	University of California
US	United States
USAMBRDL	US Army Medical Bioengineering Research and
	Development Laboratory
USAMRDC	US Army Medical Research and Development Command

#### INTRODUCTION

The purpose of this document is to provide an Equipment Plan for the AMTR facility, with LAIR as the expected location. This plan will consider the identification, acquisition and installation of equipment and include "debugging" through continuing routine testing operations for ten years. This Equipment Plan is consistent with the projected AMTR requirements identified in Task 2, the QA Plan (Task 6), the Facility Plan (Task 5), the Technical Plan (Task 3) and Management Plan (Task 9). The Equipment Plan identifies resource requirements and, as such, provides input to the Resources Plan (Task 8) and the Personnel Plan (Task 7). Personnel requirements include equipment operators and personnel required for the identification, acquisition, installation and maintenance of equipment.

The Equipment Plan consists of three separate phases:

- 1. The time prior to turnover of the facility to the operational teams.
- 2. The first five years of operational testing.
- 3. The second five years of operational testing.

The second five years of operational testing takes into account equipment replacement requirements and changes in testing requirements (both in the numbers of tests and the types of tests) that are performed. The plan provides all the equipment that will be required by the AMTR facility to conduct toxicological testing of good quality.

#### Background

The Equipment Plan includes equipment identification, acquisition and installation considerations phased over time. Special consideration was given to support service options, inhalation chambers and their supporting equipment, the sharing of equipment within the AMTR facility, the utilization of excess equipment, and the compatibility of equipment with the facility.

#### Scope of Plan

The scope of the Equipment Plan is as follows:

- 1. Identify all equipment necessary for:
  - a. Each potential area/laboratory (module) that is required in a complete capability AMTR facility.
  - b. The LAIR AMTR facility required to meet the requirements developed in Task 2 for ten years.
- 2. Plan for the acquisition of all equipment.
- 3. Plan for installation of all equipment, taking into consideration the facility design features which impact equipment movement, use and installation.

- 4. Identify the external support services that are the best candidates for quality performance. Evaluate support service options. In particular, evaluate the options of performing all or part of the analytical chemistry support external to the AMTR facility.
- 5. Identify the personnel needs (by type, but not number) for all equipment related activities, including equipment identification, procurement, installation and maintenance.
- 6. Identify equipment redundancy needs and replacement considerations for ten years of operation.

#### Approach

The approach used in performing this task is described below. The organization of the effort is described and the team members participating in the effort are identified.

Table 1 lists the nine subtasks included in the equipment plan and the individuals participating in each effort. There are nine subtasks included in the Equipment Plan task.

The approach used is depicted in the overview flow diagram, Figure 1. Figure 1 shows that the input information from Task 2, AMTR Requirements, is used to determine which modules and how many of each module are required for the facility during each phase. Input data from Task 5, Facility Plan, provides the critical dimensions of the facility such as ceiling heights, elevator sizes, and stairwell dimensions that impact the ability to move equipment throughout the facility and initial equipment installation. The equipment identification was performed by determining the requirements for each module. This provided a listing of equipment function, estimated cost, operator requirements, capacity, expected life, size, voltage requirements and special requirements for each of the 61 modules that would be needed to provide an AMTR facility with a total capability.

The input information for the equipment lists was prepared by individuals who have firsthand experience with similar modules at high quality "state-of-the-art" facilities under their responsibility. The organizations participating in the equipment list formulation included: consultants from ICAIR Systems Division of Life Systems; representatives from Brookhaven National Laboratory, Segner and Dalton, UC-Davis, SRI International and MRI; and LSI staff members.

Equipment on the lists was designated into the categories of essential, desirable or ideal. Essential equipment includes all items that a module must have to satisfy QA and GLP requirements. Desirable equipment items are those that the individuals preparing the equipment list felt they would like to have in the module but which are not absolutely critical to meeting minimum requirements. Ideal equipment includes those items that would be included if funding restrictions did not exist and if the facility were going to be fully equipped and comparable to the leading laboratory of its type.

Equipment compatibility with the facility was determined by considering the weight, size and special requirements specified for all items. Excess Govern-

#### TABLE 1 SUBTASKS AND PERSONNEL

	Subtask	Personnel
1.	Identification Plan	(a)
2.	Acquisition Plan	R. Alban, E. Linaburg, G. Schiefer
3.	Installation Plan	
4.	Inhalation Chamber Design and Supporting Equipment Study	G. Schiefer, R. Drew, R. Shiotsuka, W. Wagner, J. Last
5.	Investigation of Equipment Compatibility with Facility	R. Alban, S. Seymour, W. Craft
6.	Demarcation of Responsibility for Equipment	R. Reuter, G. Schiefer
7.	Evaluation of External Analytical Chemistry and Other Externally Provided Support Services	R. Alban, E. Linaburg, L. Wolfe, J. Lantz
8.	Phased Equipment Requirements	R. Wynveen, R. Reuter
9.	Identification of Essential, Desirable and Ideal Equipment	(a)

<sup>(</sup>a) G. Schiefer, R. Alban, J. Kowalski, D. Jones,

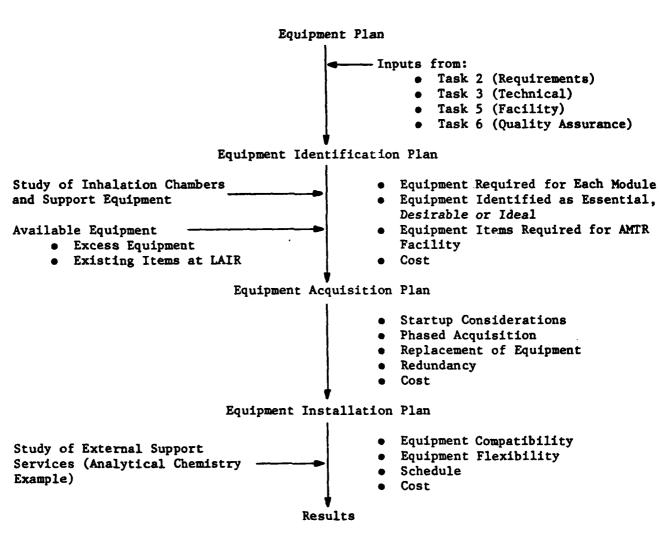
S. Unwin, R. Shiotsuka, K. Killam, W. Kilgore,

G. Podrebarac, J. Jackson, E. Williams,

B. Kirkhart, F. Metz, I. Elwood, D. Takade,

C. Mitoma, S. Graves, E. Linaburg, D. Hsieh,

J. Powell



- Total Equipment Cost to Task 8, Resources Plan
  - Cost per Module
  - Cost for the Facility
- Personnel Needs to Task 7, Personnel Plan
- Space and Utility Needs to Task 5, Facility Plan
- External Services Results to Task 3, Technical Plan

FIGURE 1 OVERVIEW OF EQUIPMENT PLAN

ment equipment availability and procedures for obtaining it were obtained by contacting the DOD, DA and GSA Property Disposal Offices. A list of major existing equipment items within LAIR was obtained by a walk-through survey of LAIR, review of drawings and property books and interviews.

The subtask on external support services was addressed as follows:

- 1. A list of the permanent and support services was developed.
- 2. The best candidate services to be provided externally were identified by using a set of evaluation criteria.
- 3. Other federal agencies in the San Francisco Bay area utilizing contract support services were contacted to get a list of recommended or approved performers for analytical chemistry.
- 4. A list of potential analytical chemistry contractors was obtained from telephone directories.
- 5. The LSI files on analytical chemistry laboratories in the San Francisco Bay area were reviewed.
- 6. The responses of interested firms to the Commerce Business Daily Notice concerning GOCO operation of the AMTR facility were reviewed.

The approach used for acquisition divided it into three phases as mentioned earlier. Equipment installation considered both item location and scheduling of the installation.

#### Assumptions

The assumptions below were made to facilitate preparation of the Equipment Plan:

- 1. Technology and regulatory changes are not considered in determining the types of equipment required for the facility.
- 2. Equipment requirements for all AMTR modules are identified.
- 3. Medium quality equipment will be used in the facility.
- 4. The AMTR Facility will be outfitted with all equipment needed to perform the testing requirements identified in Task 2.
- 5. For cost estimation none of the existing minor equipment items at LAIR are considered to be available for shared use or to be provided to the AMTR facility.
- 6. Only major items of existing LAIR equipment are considered for use in the AMTR facility.
- 7. Equipment purchased for the AMTR will require replacement either once or not at all during the ten year operational period.

- 8. Cost for minor equipment items is summarized as a total cost for miscellaneous items for each module.
- 9. Equipment acquired for the AMTR will not be shared with other activities inside LAIR. Likewise, no equipment is expected to be available for shared use from activities that may be ongoing at LAIR.

#### **Definitions**

Permanent Service - Functions essential to an AMTR facility that will not be provided externally.

Support Service - Those AMTR functions that can effectively be performed internally or externally to the facility.

San Francisco Bay Area - A 50 mile radius of the LAIR.

Built-in Equipment - Fixed, nonmovable equipment that is either connected to the floor, walls, or ceiling and/or is connected to a piped water line, fixed power line, fixed wastewater line, or intake or exhaust vents.

Equipment Categories - Classification of items into built-in (scientific and nonscientific) and movable (scientific and nonscientific).

Scientific Equipment - Equipment required to perform laboratory AMTR experiments.

Nonscientific Equipment - Equipment needed in the AMTR facility but not critical to laboratory experimental studies (such as office furniture and administrative equipment).

Startup - Time period starting with the acceptance date of the facility and ending when the facility achieves operational status.

Movable Equipment - Items that do not require alteration of the facility to be relocated. Items that can be installed or relocated without the services of special personnel.

Existing Equipment - Items that are on the property books of the LAIR.

Equipment Identification - Process of selecting the item, its specifications, manufacturer and model number but not designating the vendor.

Equipment Acquisition - All ordering and receiving activities for selected items.

Equipment Installation - The placement and connection of items in their designated location such that they are ready for turnover to the operational staff.

Scheduled Maintenance - Periodic servicing required to keep equipment functioning efficiently.

Unscheduled Maintenance - Service and repairs acquired because of an equipment failure or malfunction.

Inhalation Chamber - The enclosure and its connections used to house the laboratory animals during inhalation toxicology studies.

Inhalation Chamber System - The inhalation chamber and all supporting instrumentation, controls, test agent generators, air supply and exhaust air piping, filtration and conditioning equipment, and cages and racks required to expose laboratory animals for inhalation toxicology studies.

Equipment Life - The length of time that an item is expected to perform satisfactorily when it receives scheduled maintenance and is operated by a properly trained individual.

External Support Services - Those functions that can be provided by a performer outside of the AMTR facility and satisfy quality requirements.

Lead Time - Time between start of the acquisition process and delivery of the item at its destination.

Redundancy - Backup items necessary to avoid loss of capability.

Debug - Efforts to correct initial defects or malfunctions in equipment.

#### Policies

The following policies guided development of the Equipment Plan:

- 1. U.S. manufactured equipment will be utilized whenever possible.
- 2. "Off-the-shelf" equipment will be used to the maximum extent feasible, compatible with fulfilling the facility's mission.
- 3. Techniques to provide for high quality AMTR, reduce labor intensive functions, provide for compliance with QA requirements and GLP will be integrated into the Equipment Plan.
- 4. Medium quality equipment will be used in the facility.
- 5. Excess Government property will be used, but only when it does not compromise test quality.
- 6. Overall equipment cost (procurement, operational or maintenance and replacement cost) will be minimized consistent with meeting QA and GLP requirements.

#### Guidelines

Guidelines to be followed in the Equipment Plan include:

- Equipment will be provided that does not limit either the amount of testing or achievement of acceptable test quality.
- 2. The planning horizon shall be ten years of operation, divided into three phases (as discussed earlier).

- 3. Two criteria for equipment selection will be flexibility and adaptability to minor procedural and protocol changes over the decade.
- 4. Equipment with a life expectancy of at least ten years will be procured, if available at a competitive price.

#### Interrelationships with Other Tasks

Figure 1, in addition to depicting the plan overview, also indicates the interrelationships between the Equipment Plan and other tasks.

#### Facility Plan (Task 5)

The Equipment Plan's interrelationships with the Facility Plan include:

- 1. Ensuring that all built-in equipment noted in the facility module drawings are included in the equipment lists.
- 2. Ensuring that the amount of equipment such as racks and cages listed for each equipment module is consistent with the equipment depicted and the assumptions made in preparing the module facility designs.
- 3. Identifying large equipment items that may impact a module's location within the facility and facility renovation design considerations. Alternatively, selecting smaller size equipment modules or equipment that can be disassembled to accommodate relocation or initial installation.
- 4. Identifying built-in equipment to provide for its timely availability and accommodate the utility and space requirements in the facility design.

#### Resources Plan (Task 8)

The Equipment Plan provides cost information to the Resources Plan for all aspects that are both associated with equipment and included in the scope of the Equipment Plan.

#### Quality Assurance Plan (Task 6)

The Equipment Plan interrelationship with the QA Plan includes providing the necessary equipment to carry out the QA program proposed in the QA Plan. This provides for equipping the QA Laboratory, including GLP compliance from an equipment standpoint.

#### Personnel Plan (Task 7)

The Equipment Plan's interrelationship with the Personnel Plan includes identifying the operator of each equipment item listed. The list of personnel types needed for equipment operation is incorporated directly into the Personnel Plan.

#### EQUIPMENT IDENTIFICATION PLAN

#### Assumptions

The following assumptions were made regarding identification of equipment:

- 1. All scientific equipment items greater than \$1,000 in value are itemized on equipment lists for each module.
- 2. The search for excess equipment through other Government agencies will consider only major, movable scientific equipment items that can be transferred to the AMTR facility property books.
- 3. All other things being equal, movable equipment will be selected rather than built-in to provide flexibility and reduce installation costs.
- 4. Nonscientific equipment will be priced in a lamp of ligure for each research/testing module.

#### Schedule

Figure 2 is the proposed schedule for equipment identification, acquisition and installation. Initial equipment identification determines the items required for the first five years of operation. A second process identifies new or expanded AMTR requirements for the second five years of operation. Table 2 lists the major milestones on the schedule and provides the rationale for the schedule.

#### Strategy

Strategies to be followed in the equipment identification plan are:

- 1. Identify all equipment required for the AMTR facility over the ten year time frame.
- 2. Itemize all major equipment item requirements and provide a cost summary estimate for minor equipment items required for each module and for the AMTR facility.
- 3. For each major item provide the name, function, estimated cost, operator title, capacity, number required per module, expected life, size, voltage requirement and special requirements.
- 4. Classify equipment items as essential, desirable or ideal.

#### Identification of Existing Equipment

The following sources of existing equipment should be considered:

- 1. Major items of existing equipment at LAIR.
- Existing equipment from other Government laboratories:

FIGURE 2 SCHEDULE

ļ				10 years	ars
∑ 7-3	SOEDAL RESPONSIBILITY		OPECIMAL SCHEDULE APPROVAL		
_	•			<b>GATE</b>	-
	STATUS RESPONDENTY		LAST SCHEDULE CHANGE (DATE) (NO.) (INITIALS)	(TE) (MO.) (IM	TAILS
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		-2   -1   1   2   3   4   5   6	2 ×	6	5
	TASKS/SUBTASKS				
	Identification				
7	Existing Equipment	<u> </u>			
•	Excess Equipment				
-	New Items				
8	Acquisition				
8	Selection of Vendors	•\forall  \qu			
1	Ordering				
80	Receiving				
6	Installation				
10	Built-in Equipment				
=	Movable Equipment				
-	Debugging	\$\frac{1}{2}\$			
[]	Maintenance				
<b>*</b>	Phase 1				
15	Phase 2				
16					
17					
18					
19					
20					
	offs Milestone (see Table 2 for List of Milestones)	$\Delta$ Turnover date of facility to operational team			•
J					]

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Figure 2 - continued

# Rationale For Schedule

Task/Subtask	Time Requirement	Rationale For Time Requirement
Identification	9 weeks	1
Existing Equipment	l week	Perform inventory of existing equipment at facility - 120 hours - 3 persons full time - 1, week
Excess Equipment	3 weeks	Excess equipment checks at DA, DOD, GSA levels, computer runs (2 weeks turnaround time), evaluation of output - 80 hours - 2 persons - 1 week
New Items	3 weeks	600 items @ 2 hrs/item - 1200 hours - 10 persons full time - 3 weeks
Acquisition	39 weeks	1
Selection of Vendors	10 weeks	Critical time factor is specification package and bid/proposal submission and evaluation for special items such as inhalation chambers
Ordering	3 weeks	600 items @ 2 hours/item - 1200 hours - 10 persons full time - 3 weeks
Receiving	29 weeks	Special items (inhalation chambers, generators, computers) will require up to 29 weeks
Installation	26 weeks	) 1
Built-in Equipment	26 weeks	Schedule tied to building renovation schedule
Movable Equipment	1 week	Utilization of a commercial moving company

Figure 2 - continued

Rationale For Schedule - continued

Task/Subtask Debugging Maintenance	Time Requirement Ongoing Ongoing	Will require 3 months for more complex items such as a GC-MS or inhalation chamber system Continuing process
Phase 1	5 years	As planned
Phase 2	5 years	As planned

#### TABLE 2 LIST OF MILESTONES

Number	Milestones
1	Decisions on Facility Plan, testing requirements and the scope of testing efforts finalized.
2	Decision made on initial external support service utilization.
3	Reevaluation of equipment requirement for Phase 2 started.
4	Existing equipment to be utilized identified.
5	Equipment required for Phase 1 but not already available to AMTR identified.
6	Identification of Phase 2 items completed.
7	Bids evaluated and/or vendors selected for all procurements.
8	Bids evaluated and/or vendors selected for Phase 2 procurements.
9	Orders placed for inhalation chambers and supporting equipment.
10	Orders placed for Phase 2 long lead items.
11	All inhalation chambers delivered to facility.
12	All built-in equipment delivered to facility.
13	Installation completed for Phase 1.
14	Installation completed for Phase 2.
15	Facility inspected and approved for transfer to operators.
16	Debugging of Phase 1 equipment completed.
17	New modules and equipment delivered to operators.
18	Operational phase begins.
19	End of Phase 1.
20	Start of Phase 2.

- a. Within both the San Francisco Bay area and throughout the nation.
- b. At other DA, DOD and non-DOD laboratories.

Table 3 contains a list of major items of equipment potentially available to the AMTR facility at LAIR.

The availability of all DA and DOD excess equipment can be obtained for the computer-based equipment reutilization program. To use this system, federal stock numbers for each equipment item must be identified from specific DOD item managers or catalogs. Once federal stock numbers are identified the Defense Property Disposal Office (DPDO) will initiate computer searches for equipment items on a national or regional basis and obtain information on the availability of such equipment. Requisitioning procedures can be initiated when acceptable equipment items are found.

A second source of excess DOD equipment is through the Defense Logistics Service Center (DLSC). Both DPDO and DLSC reportedly have access to the same lists of excess equipment items.

The availability of excess equipment from non-DOD government agencies can be found by using the GSA property disposal offices. The GSA maintains a separate listing of high value items (those in excess of \$100,000). This computerized listing uses the federal stock numbers for item identification.

#### Equipment Requirements for Modules

Appendix 1 contains an example of the equipment list used to itemize all major items for each module required for a complete AMTR facility. The summary cost of minor items is also listed for each module. Therefore, the total cost represents the acquisition cost for all equipment identified by the experts who prepared the list. Equipment identification includes the item name, function, range of estimated cost, operator requirements, voltage information and special requirements.

#### Inhalation Chamber and Supporting Equipment

The approach used to obtain information on inhalation chambers was to contact the existing AMTR facilities that have the best inhalation toxicology equipment and also to contact manufacturers/designers of inhalation chambers directly. Product literature was obtained from manufacturers/designers. Inhalation toxicology experts from LSI's ICAIR Systems Division (Drs. Robert Drew, Ronald Shiotsuka, Jerold Last, William Wagner and Maurice Weeks) identified the best facilities, leading manufacturers/designers and indicated considerations, features and "lessons learned" from their experiences. A questionnaire was developed to collect comprehensive and standardized information on inhalation chambers and supporting equipment from the manufacturers and facilities. This questionnaire is included in Appendix 2.

Objectives of the survey were to:

#### TABLE 3 MAJOR EQUIPMENT ITEMS POTENTIALLY AVAILABLE AT LAIR

- Racks
- Cages
- Non-scientific Equipment, Administrative Furniture (e.g., Files)
- Laboratory Benches
- Laboratory Balances
- Installed Hoods
- Necropsy Room Equipment
- TOXSYSTEM (Hardware and Software) (a)
- Data General Eclipse C330 Computer (a,b)
- Electron Microscope
   Cage Washer
- Animal Feed and Storage Items
   Pathology Laboratory Items (a)
- Radioisotope Counting Items (a)
- Transformer
- Diesel Generator
- Fuel Storage Tank
- Parallel Switch Gear
- Deionizer
- Centrifugal Chiller

Trained operator currently available within LAIR Available for on-site scientific computation efforts

- 1. Determine the state-of-the-art, design options and availability of inhalation chamber systems.
- 2. Determine the manufacturers/designers most active in innovative systems.
- 3. Collect information on and evaluate existing systems' applicability and adaptability to the Army's AMTR requirements.

The strategy followed was to get confirmatory information from several facilities utilizing similar chamber systems whenever possible. This method also avoided reliance, wherever possible, on manufacturers'/designers' information that may be inherently biased. Only those inhalation toxicology testing facilities with an excellent national reputation were contacted. A basic list of inhalation toxicology testing facilities was obtained from the 1977 report of the Sub-Committee on Inhalation Toxicology of the Department of Health, Education and Welfare, Committee to Coordinate Toxicology and Related Programs. Another source of potential laboratories was obtained from a review of existing and past USAMRDC and NTP contractors. The following facilities were contacted:

- 1. Brookhaven National Laboratory
- 2. Chemical Industry Institute of Toxicology
- 3. National Institute of Environmental Health Sciences
- 4. Environmental Protection Agency, Research Triangle Park
- 5. Environmental Protection Agency, Center Hill Facility, Cincinnati
- 6. National Institute for Occupational Safety and Health, Cincinnati
- 7. Lovelace Inhalation Toxicology Research Institute
- 8. Hazelton Laboratories, Inc.
- 9. Battelle Columbus Laboratories
- 10. U.S. Army Environmental Hygiene Agency
- 11. Toxigenics, Inc.
- 12. Litton Bionetics, Division of Litton Corporation
- 13. IIT Research Institute
- 14. Monsanto Company
- 15. The Upjohn Company
- 16. University of California, Davis

The following manufacturers of inhalation chambers were identified and contacted:

- 1. Charles Spengler and Associates
- 2. Hazelton Systems, Inc.
- 3. King Lar Company
- 4. Wahmann Manufacturing Company
- 5. Young & Bertke Company

#### The results of the study are summarized as follows:

- Manufacturers do not limit themselves to specified, off-the-shelf designs. For most applications a basic design concept is tailored to the specific needs of the facility by getting input from a consultant or the purchaser.
- 2. If chamber reliance is discounted as a variable, the major differences between chambers (not chamber systems) are in shape, in ability to expose either a whole animal or just its nose and in design features to accommodate animal loading, unloading and care.
- 3. Inhalation chamber fabrication and design is a business with a small market, measured in both number of transactions and total dollars. Hazelton Systems, Inc. is the largest business active in chamber fabrication (based on total sales).
- 4. Either racks and cages should be purchased in conjunction with the chambers or the specifications of existing cages and cages that will be used should be previously determined to avoid a compatability problem. Certain special racks are available to reduce the effect of uneven distribution of the test agent inside the chamber and avoid intercage contamination by feces and urine droppings from upper cages to lower ones.
- 5. Chamber manufacturers routinely fabricate chambers to the buyers' specifications. An average lead time of three months was quoted by the manufacturers for orders of up to up to 15 chambers. Longer periods would be required if more than 15 chambers were ordered from a single manufacturer. Purchasers of chambers indicated that six months, not three, is the average delivery time they experienced. With an adequate specification package several manufacturers could fabricate identical units. One manufacturer could make the acute chambers, another the subchronic and a third the chronic.
- 6. Special Army requirements are associated with short-term, intermittent, high-level troop exposures. A special team of chamber design experts and toxicologists should be used to design the needed chamber systems. Such chamber systems will be influenced by the inhalation toxicology protocols used. Therefore, protocol determinations must precede chamber design.
- 7. Support equipment probably has greater impact on chamber system capability than chamber design.

- S. Upjohn is patenting a new chamber design that has a low height to chamber volume ratio as one of its major features. This is particularly attractive relative to accommodating chambers into existing LAIR buildings that may not have sufficient floor to ceiling distance to accommodate certain conventional chamber designs.
- 9. Chambers can be categorized into those that are movable (routinely put through a washer) and those that are fixed in place (built-in) equipment.
- 10. The Hazelton 1000 chamber appears to be the chamber that is currently being produced in the greatest numbers. Because of its popularity there may be backorders. One of the principal features of the Hazelton 1000 is the use of catch pans to avoid transfer of droppings from the animals in higher cages to lower ones and to maintain an even distribution of the test agent in the filled chamber.
- 11. One of the features desired in chambers used for certain Army tests is the ability to achieve a designated level of test agent concentration rapidly and to maintain it in the chamber. The best approach for achieving this is to utilize an interactive computer that manipulates the input of the test agent and input air volume and reduces the time to equilibrium concentration to less than two minutes. The normal sequence may require 30 minutes or more to bring the chamber up to its desired concentration.
- 12. Air handling systems, both for entrance air and for treatment of exhaust air, and monitoring and control equipment are normally not provided by chamber manufacturers.
- 13. Chamber manufacturing remains a highly specialized field with relatively few manufacturers and numerous tailored but basically similar units.
- 14. As concerns for environmental quality, quality assurance and personnel safety increase, the state-of-the-art of inhalation chamber systems have progressed to include improved double filtration systems for exhaust air and automated monitoring and control, with data storage retrieval and alarms. The chambers are frequently housed inside of separate rooms or hood enclosures with air pressure relationships that provide a double safeguard of protection (the chamber has the lowest pressure, the enclosure the next lowest pressure and the general room area the highest pressure). This provides for inward air flow into areas with greatest contamination potential. Some chambers are serviced by special mobile service modules that protect the ambient air during chamber servicing.
- 15. Some measures have been taken to provide inhalation exposures other than with a chamber. Primates and certain other larger animals can wear special exposure helmets. Such systems are adequate for short-term exposures but are not practical for long-term studies.

16. Current chamber designs accommodate the numbers and types of animals called for in standard protocols. Chambers used for regulatory testing compliance purposes must be able to handle the standard number of animals, a sufficient number of chambers must be available to handle the number of dose and control groups required by the protocol.

#### Impact of Testing Requirements on Equipment

The types of tests to be performed in the AMTR facility will impact the equipment requirements by determining the types of modules required.

The number of tests performed per unit of time will determine the number of modules needed (but does not affect the equipment contained in each module).

#### EQUIPMENT ACQUISITION PLAN

#### Assumptions

The following is assumed regarding equipment acquisition:

- 1. Equipment will require replacement once, at most, during the ten-year period.
- 2. For estimating equipment acquisition costs, it is assumed that items will be procured only twice during the ten years (prior to the start of operations and at the end of five years of testing).
- 3. Unless otherwise specified, all equipment items will be available within 2½ months of their requisition date. This assumes that equipment acquisitions will not be governed by normal government requisitioning procedures and will be handled by the facility contractor.
- Only items of equipment costing \$1,000 or more each will be itemized.

#### Schedule

The schedule for acquisition shown in Figure 2 is arranged to have the equipment available to enable the startup of the facility. Built-in items of equipment will be acquired and delivered to the site in time for installation during the renovation process. All other equipment required for the first five years of operation will be available as soon as facility renovation is completed and the facility is ready to be turned over to the operational team to initiate startup activities. Equipment acquisition for the second five years will include equipment to accommodate any increase in testing requirements, to accommodate requirements for new types of testing and to provide replacement items for equipment that is obsolete or no longer effective.

#### Start-Up

The Equipment Plan focuses on ways of expediting the identification and acquisition of items so as to reduce the lead time. Equipment manuals can be obtained

in advance to familiarize operators with the equipment. Consideration can be given to hiring personnel who have experience with the specific equipment items being procured. Operators could receive training at another AMTR facility or at the manufacturer's facility prior to equipment delivery to facilitate startup.

Testing should be scheduled to phase in the use of complex equipment. Special QA consideration may be appropriate during startup. A scheduled maintenance program will be instituted upon opening of the facility. Wherever possible, units of the same model and manufacturer will be procured throughout the facility so that the maintenance personnel and operators need be familiar with the minimum number of items. This will also reduce spare parts inventory requirements. Standard operating procedures should be developed and used exclusively for the startup phase.

#### Phase One

After all equipment necessary for Phase One of testing has been acquired and installed, it will be turned over to the facility's operational staff.

#### Phase Two

Phase Two covers the second five years of operation. During Phase Two, an evaluation of the available equipment will be made to ensure that all replacement acquisition considers past performance records, maintenance and operational cost. Evaluations will also be made to note technology advancements that reduce operator skill requirements or operator time, improve quality or reduce costs. Equipment in acquisition during this phase will be concerned with replacing obsolete or worn-out items of equipment, providing additional equipment to meet new testing requirements, and providing equipment to meet requirements for additional tests (equip more modules).

#### Equipment Types

#### Office Furniture and Other Nonscientific Equipment

Office furniture and other nonscientific equipment items are either itemized on the respective module equipment lists or included as a lump sum cost per module if their cost does not exceed \$1,000.

#### Movable Scientific Equipment

Movable scientific equipment is acquired for use within a specific module. It may be desirable to use the equipment at several different locations within the module but it is not expected that equipment in one module will be available to meet the equipment requirements of another module. Ideally, movable scientific equipment needs to be available when the facility is turned over to the operational staff.

#### Built-In Equipment

Built-in, scientific and nonscientific equipment is required to be available in sufficient time to allow it to be integrated into the facility renovation

schedule. Consideration should be given to providing all built-in equipment required for the full ten years of operation during the renovation phase. This may be advantageous because of the difficulty of installing built-in equipment once renovation is completed, the disruption associated with installing built-in equipment later when the facility is in an operational testing mode and finally because certain renovation may not proceed until equipment is installed.

#### Equipment Redundancy

Equipment redundancy will be considered:

- 1. To provide immediate replacement of items essential to ensuring that testing is not interrupted and that major research investments are not jeopardized.
- 2. To accommodate fluctuations in workload and provide replacement units during scheduled or unscheduled maintenance.
- 3. To provide safety protection to operational staff and the public by precluding discharges of chemical or biological hazardous material in excess of acceptable levels.

#### EQUIPMENT INSTALLATION PLAN

#### Assumptions

- 1. Equipment will be available as needed for installation.
- 2. Built-in equipment will be installed during facility renovation.
- 3. Utility requirements for equipment will be provided within the facility design.
- 4. Debugging is a separate function and is not part of the installation.

#### Schedule

The schedule for installation is included in Figure 2. Installation occurs during renovation and at the start of Phases One and Two.

#### Strategy

The strategy of the equipment installation plan is to anticipate problems and avoid or minimize them, and to have the equipment ready for the startup of operational activities.

#### Equipment Compatibility with Facility

Principal aspects of compatibility relates to:

1. Movable equipment that must be moved from floor to floor using the elevator systems and corridors or moved between rooms on the same floor through doorways and corridors.

- Equipment that does not exceed the weight limitations for certain floors.
- 3. Equipment that does not exceed available utility requirements.
- 4. Equipment that has a height greater than the LAIR floor to ceiling distance.

Table 4 lists the largest and heaviest equipment items that could present compatiblity problems. Options include using certain smaller units if available, assembling built-in equipment in the location in which it will be used or using equipment that consists of several component parts. Finally, consideration can be given to using stationary equipment and bringing the samples or test material to the equipment rather than moving the equipment to the sample location. No equipment items exceed the weight limitations of LAIR. Inhalation chambers will require additional air handling and exhaust hardware, as will the many hoods.

#### Flexibility Considerations

Movable equipment should be utilized instead of built-in equipment if an option exists and costs are comparable. Built-in equipment can be fitted with quick disconnects. Heavier movable equipment should be mounted on rollers.

Equipment items with larger capacities can be considered for purchase to accommodate increased requirements. The identification and utilization of external support services will provide considerable flexibility. Cross training of personnel on several different equipment items will also provide flexiblity, as will the selection of multipurpose equipment.

#### SUPPORT SERVICES

#### Assumptions

- External performance of support services is an alternative performance mode for all services, except for those designated as permanent services.
- 2. Selection of external performers will be made on the basis of cost, quality and schedule.
- 3. External performance will be considered as a means of fulfilling certain QA needs and handling of peak workloads.
- 4. Any external support services will be provided in a manner that does not negatively affect testing quality and schedule.

#### Schedule

 An initial review of external support services will be made prior to equipment acquisition and facility design. This will to avoid purchasing unnecessary equipment and will maximize utilization of space for permanent services.

TABLE 4 LARGE(a) EQUIPMENT ITEMS FOR AMTR FACILITY

Equipment Item	Dimensions (b)
Safety hood system(d)	72 x 30 x 84
Cage rack(c)	$72 \times 30 \times 72$
Inhalation exposure chamber for	
acute studies with rodents (e)	$30 \times 30 \times 84$
Inhalation exposure chamber for	
subchronic studies with rodents (e)	36 x 36 x 84
Special purpose inhalation exposure chamber(e)	72 x 36 x 84
Inhalation exposure chamber for chronic studies	
with rodents and for primate exposures (e)	72 x 72 x 132
Walk-in freezer(d)	$180 \times 120 \times 96$
Walk-in refrigerator (d)	$108 \times 144 \times 84$
Hood inclosure(d)	$120 \times 120 \times 96$
Feed pallet (C)	$96 \times 24 \times 24$
Cold box (d)	96 x 96 x 84
Primate housing unit (d)	$30 \times 30 \times 80$
Dog pens <sup>(u)</sup>	48 x 96 x 72
Refrigerator (C)	72 x 96 x 84
Rack washer(d)	84 x 90 x 96
Tunnel type cage washer and dryer	$30 \times 360 \times 72$
Autoclave (d)	36 x 72 x 96
Freezer(c)	84 x 33 x 84
Magazine rack(e)	36 x 12 x 82
Bookcase <sup>(e)</sup>	36 x 12 x 82
Mirror(d)	$36 \times 0.5 \times 72$
Electric pallet cart(c)	33 x 26 x 92
Shelves <sup>(e)</sup>	36 x 24 x 85
Table <sup>(e)</sup>	30 x 72 x 29
Hobart mixer (50kg) (d)	48 x 60 x 60
Pyrolyzer	Various
Walk-in hood <sup>(a)</sup>	90 x 42 x 108
Worktable w/sink(d)	84 x 29 x 37
Transformer <sup>(d)</sup>	80 x 96
Diesel generator (d)	48 x 1400 x 72
Parallel switch gear (a)	36 x 54
Fuel storage tank (d)	240 x 96 x 60
Muffler(d)	120 x 36
Water softener (d)	120 x 300 x 180
Deionizer(d)	180 x 360 x 300
Waste water treatment system(d) Centrifugal chiller(d)	<b>Varia</b> ble 156 x 216 x 96
Centrifugal chiller	
Air supply system(")	Various Various
Air exhaust system <sup>(d)</sup>	348 x 120
Boiler, primary (d)	120 x 96
Roiler, secondary (")	91 x 42
Steam condensation tank(u)	91 x 42
Expansion tank(d)	71 A 44

<sup>(</sup>a) Items with at least one dimension ≥ 72 in. or items with all dimensions ≥ 48 in.

<sup>(</sup>b) Width x depth x height in inches

<sup>(</sup>c) Movable equipment items

<sup>(</sup>d) Built-in equipment

<sup>(</sup>e) Movable or built-in depending on design chosen

- 2. Use of external support services should be reexamined at least annually so as to reflect the current status of in-house personnel availability, cost, external support service availability and the changes in the number and types of testing requirements.
- 3. Selection of external support services will be consistent with government procurement regulations and be based on the solicited responses to requests for proposals advertised in the Commerce Business Daily.

### **Objective**

The objective of using external support services is to provide for efficient operation of the facility by avoiding the purchase, operation and maintenance of expensive equipment that is not fully utilized. A further objective is to avoid limiting the capabilities of the AMTR facility by having only in-house performance.

### Strategy

The modules necessary make up a complete AMTR facility were grouped into two categories: (1) permanent service modules and (2) candidates for external support services. The permanent services are essential to the AMTR facility and are not candidates for external support.

Support services were evaluated using the following criteria:

- 1. Expected availability of the external support.
- Relative cost of providing the service externally versus internally.
- 3. Schedule requirements.
- 4. Expected quality of external support.
- 5. Space requirements for providing the service internally.
- 6. The number and type of personnel required, their skill levels, general availability, etc.
- 7. Equipment requirements (cost, expected use, special requirements, maintenance, etc.).

Table 5 provides a preliminary evaluation of support services using the criteria listed above.

# External Analytical Chemistry Support

The recommended approach would limit the evaluation of analytical chemistry support services to facilities in the San Francisco Bay Area, since sample delivery, preservation and turnaround time preclude remote performance of routine support. Local services will also reduce shipment costs and time and allow for face-to-face meetings and site visits.

TABLE 5 EVALUATION OF SUPPORT SERVICES

		Equipment			Ses	Service		Personnel	Total Control	Facility	
			Infrequent	Outside	Outside availability	Schedule			Lebor		
	High cost Rems reg'd	Maintenance cost Nigh	utilization expected	Local	National	demends	Required	Specialized training	intensive activities	Space reg'l, large(a)	Special Considerations
Pathology Laboratory	YES	YES	Ş	YES	YES	O <sub>Z</sub>	YES	YES	YES	YES	Most applicable to reading sildes.
Clinical Chemistry Laboratory	YES	YES	Q.	YES	YES	NO	YES	YES	YES	YES	Sample preservation and changeable work- loads need to be considered.
Animal Breeding	S S	ON O	YES	NO	YES	NO	NO	NO	YES	YES	Special strains and special handling may preclude external support.
Voterhary Medicine	NO	NO	YES	YES	YES	NO	NO	YEB	NO.	YES	Primarity a personnel service, with veterinarian coming into facility.
Analytical/Synthetic Chemistry Laboratory	YES	YES	ON	YES	YES	YES	YES	YES	YES	YES	Can be used for QA support, special studies or a capability to handle overfoad.
Automated Data Processing	YES	YES	ON	YES	YES	ON	YES	YES	YES	YES	Safeguarding of classified information may be required.
Rediochemistry	YES	YES	YES	ON	YES	ON	ON	YES	ON	ON .	Rediclabeling of com- pounds available at limited number of focations.
Equipment Maintenance	NO NO	ON	YES	YES	YES	ON	NO	ON	ON ON	ON	Selecting external support will involve "house-calls" for some maintenance.
Laundry	NO NO	Q.	ON	YES	YES	SN SN	YES	NO	YE8	Q.	Storage areas will be required if an outside service is selected.

(a) Module area greater than 2000 ft²

A compilation of firms providing analytical chemistry services is available from a review of LSI files on analytical laboratories, referrals from ICAIR Consultants, referrals from the laboratories used or certified by the Regional Environmental Protection Agency and the California Department of Health and a review of the San Francisco area telephone directories.

Written inquiries and telephone requests were made to candidate firms to collect information on their general interest in performing such work, their availability, approximate cost and scope of capabilities offered. Reviews of equipment lists and personnel resumes and contact with customers who have purchased similar support is a technique that can be used to further screen performers and develop a bidders list.

# Preliminary Results

The San Francisco Bay Area analytical chemistry laboratories provide an available capability for a full spectrum of analytical chemistry support anticipated at an AMTR facility. As the desired level of sophistication of chemistry procedures increases, the resulting number of qualified laboratories decreases. The most comprehensive chemistry capability in the area, as reflected in the experience, staff, equipment and facilities dedicated to analytical chemistry, is at SRI International.

A two-stage procurement process may be advisable, using the first stage to identify qualified bidders and the second stage to select performers on the basis of technical and cost analyses. A task order level of effort contract is advisable to accommodate specific needs that cannot be foreseen when the contract is negotiated.

## Analysis of Options

Performance of analytical chemistry totally in-house would:

- 1. Limit QA to a completely internal program.
- 2. Would not provide for a capability to accommodate peak work loads.
- Require major expenditures for equipment and equipment maintenance.
- 4. Require space.
- 5. Require operator staff and management personnel.
- 6. Provide a capability very responsive to the needs of the AMTR facility.

Performance of analytical chemistry totally externally would:

- 1. Require contract monitoring and administration.
- 2. Sacrifice some control over personnel actually performing the tests.

- 3. Be limited to the scope of the contract.
- 4. Require a sample pickup system (coding, containers, recordkeeping).
- 5. Reduce in-house personnel requirements and eliminate certain equipment requirements and the need for certain laboratory capabilities.

Combination of in-house and external analytical chemistry support would:

- 1. Provide a technique for accommodating peak workloads.
- 2. Provide a capability that could be used for the QA program.
- 3. Provide management with an alternative case by case option of assigning work.

#### **EQUIPMENT COST**

The equipment cost for each module for Phase One (the first five years of operation) is listed in Table 6. Provided in this table are the equipment costs from vendors, the labor costs associated with identifying, procuring, installing and debugging the equipment and the total cost of equipment maintenance for five years. Table 7 provides the equipment costs for each module associated with Phase Two (the second five years of operation). Phase Two costs are limited to the associated costs of replacement and continued maintenance of all equipment. Table 8 identifies the high cost items (those with a vendor cost of \$20,000 or greater).

#### CONCLUSION

Equipment identification, acquisition, installation, debugging and maintenance represent a complex effort that requires careful planning and implementation to ensure efficiency, effectiveness and timeliness. These efforts must be co-ordinated and integrated with the planning and implementation of other tasks. The equipment is only one piece in the puzzle, but if not handled properly the other "pieces" of the facility will not join together into an optimal AMTR facility.

#### RECOMMENDATIONS

The following is recommended regarding equipment acquisition:

- 1. Use an approach similar to the one used for this plan in preparing the final equipment identification lists.
- 2. If time is critical consider having a contractor assist in the equipment acquisition process.
- 3. Identify those items that require high-level, long approval paths (e.g., ADP equipment) and start the approval process early enough to assure equipment availability when needed.

TABLE 6 EQUIPMENT COSTS (a) FOR PHASE 1 (\$000)

Module	Equip- ment(b)	Identifi- cation(c)	Acqui- sition(d)	Instal- lation(e)	Debug- ging(e)	Mainte- nance(f)	Total
1	83	0.88	3.1	2.6	0.10	14	104
2	83	0.88	3.1	2.6	0.10	14	104
3	83	0.80	3. 1	2.6	0.10	14	104
4	110	0.40	1.4	0.80	0.20	11	124
5 6	270	1.9	6.7	7.2	2.0	110	398
6	420	1.9	6.7	6.2	2.8	75	513
7	320	1.8	6.4	5.0	2.0	75	410
8	270	1.9	6.7	5.5	2.0	95	381
9	280	1.9	6.7	4.8	2.0	70	365
10	260	1.9	6.7	5.5	2.0	95	371
11	53	0.56	2.0	0.80	0.10	11	68
12	46	0.64	2.2	1.2	0.10	12	62
13	720	3.1	11	8.0	10	320	1073
14	390	2.0	7.0	1.0	1.6	190	592
15	390	2.0	7.0	1.0	1.6	190	592
16(g)	880	0.48	1.7	13.1	4.1	184	1083
17	270	2.8	9.8	4.0	3.7	100	390
18	69	0.64	2.4	2.0	0.10	19	93
19	69	0.64	2.4	2.0	0.10	19	93
20	96	1.3	4.5	2.5	0.10	18	122
21	330	0.32	1.1	15	0 (tr.)	170	516
22	40	0.48	1.7	2.0	0.10	17	61
23	110	0.96	3.4	0.80	0.70	50	166
24	160	1.0	3.6	3.0	0.40	39	207
25	340	2.8	9.8	2.0	0.60	90	445
26	160	0.80	2.8	0.70	1.3	75	241
27	130	1.6	5.6	29	0.50	24	191
28	100	2.3	8.1	1.0	0.90	38	150
29	200	2.5	8.7	0.80	1.0	78	291
30	1100	0.48	1.7	8.0	38	500	1648
31	200	1.1	3.9	0.60	0.60	92	298
32	93	0.48	1.7	0.80	0.20	39	135
33	16	0.32	1.1	0.10	0	7.2	25
34	10	0.56	2.0	1.0	0	0	14
35	25	0.48	1.7	1.0	0.20	12	39

<sup>(</sup>a) Costs in 1981 Dollars

continued-

<sup>(</sup>b) From Equipment Lists

<sup>(</sup>c) Number of item types x 2 hr/item type x \$40/hr

<sup>(</sup>d) Number of item types x 7 hr/item type x \$40/hr

<sup>(</sup>e) Based on estimated time required per item\_

<sup>(</sup>f) 10% of cost for listed serviceable equipment

<sup>(</sup>g) Modules 3, 7, and 10 combined along with office cost

<sup>(</sup>h) Less than \$100

Table 6 - continued

Module	Equip- ment(b)	Identifi- cation(c)	Acqui- sition(d)	Instal- lation(e)	Debug- ging(e)	Mainte- nance(f)	Total
36	6	0.88	3.1	0.10	0	0	10
37	7.6	0.64	2.4	0.10	0	0	11
38	4.5	0.80	2.8	0.10	0	1.0	9
39	2.8	0.40	1.4	0.10	0	0	5
40	24	0.16	0.56	0.10	0.10	11	36
41	3.0	0.64	2.4	0.10	0	0	6
42	1.1	0.16	0.56	0.10	0	0	2
43	1.0	0.64	2.4	0.10	0	0	4
44	2.8	0.16	0.56	0	0	0	4
45	5.4	0.32	1.1	0	0.10	2.0	9
46	2.3	0.32	1.1	0.10	0	0.60	4
47	120	0.16	0.56	0.60	0	60	181
48	330	0.40	1.4	1.4	0.10	120	453
49	128	0.32	1.1	5.0	2.0	13	149
50	800	0.08	0.28	25	5.0	400	1230
51	400	0.24	0.84	5.0	2.0	200	608
52	160	0.48	1.7	4.0	0.20	400	566
53	5.4	0.24	0.84	0.20	0.20	2.0	9
54	45	0.16	0.56	0.80	0.50	18	65
55	610	0.24	0.84	3.0	0.50	310	925
56	3.0	0.24	0.84	0.80	0	0	5 73
57	45	0.16	0.56	4.0	0.10	23	
58	65	0.48	1.7	1.3	0.10	19	88
59	47	0.16	0.56	0.50	4.0	20	72
60	7.6	0.64	2.4	0.10	0	0	11
6.1	124	0.64	2.4	3.0	0.10	36	166
62	170	2.4	8.4	5.0	0.10	43	229
63	83	0.80	3.1	2.6	0.10	14	104
	11,377	56	204	205	95	4,561	16,503

<sup>(</sup>b-f) See first page of table

TABLE 7 EQUIPMENT COSTS (a) FOR PHASE 2 (\$000)

Module	Equip- ment(b)	Identifi- cation(c)	Acqui- sition(d)	Instal- lation(e)	Debug- ging(e)	Mainte- nance(f)	Total
1	29	0.32	1.1	0(g)	0.10	14	45
2	29	0.32	1.1	0	0.10	14	45
3	29	0.32	1.1	0	0.10	14	45
4	0	0	0	0	0.20	11	11
5	92	1.2	4.2	0.20	2.0	110	210
6	92	1.2	4.2	0.20	2.8	75	175
7	92	1.2	4.2	0.20	2.0	75	175
8	140	1.4	4.8	0.20	2.0	95	243
9	140	1.4	4.8	0.20	2.0	70	218
10	140	1.4	4.8	0.20	2.0	95	243
11	0.36	0.16	0.56	0	0.10	11	12
12	0.38	0.24	0.84	0	0.10	12	14
13	520	1.8	6.2	1.9	10	320	860
14	370	1.3	4.5	0.80	1.6	190	568
15	370	1.3	4.5	0.80	1.6	190	568
16(b)	261	2.9	10	0.4	4.1	184	462
17	270	2.6	9.0	3.0	3.7	100	388
18	11	0.16	0.56	0	0.10	19	31
19	11	0.16	0.56	0	0.10	19	31
20	0	0	0	0	0.10	18	18
21	3.0	0.08	0.28	0	0	170	173
22	0	0	0	0	0.10	17	17
23	67	0.32	1.1	0.20	0.70	50	119
24	38	0.40	1.4	0.10	0.40	39	79
25	35	1.5	5.3	0.10	0.60	90	133
26	12	0.40	1.4	0.10	1.3	75	90
27	110	1.4	4.8	28	0.50	24	169
28	97	1.6	5.6	1.0	0.90	38	144
29	140	0.96	3.4	0.60	1.0	78	224
- 30	1100	0.32	1.1	6.0	38	500	1645
31	98	0.24	0.84	0.20	0.60	92	192
32	3	0.08	0.28	0	0.20	39	43
33	0	0	0	0	0	7.2	7
34	0	0	0	0	0	0	0
35	0	0	0	0	0.20	12	12

<sup>(</sup>a) Costs in 1981 Dollars

continued-

<sup>(</sup>b) From Equipment List

<sup>(</sup>c) Number of item types x 2 hr/item type x \$40/hr

<sup>(</sup>d) Number of item types x 7 hr/item type x \$40/hr

<sup>(</sup>e) Based on estimated time required per item

<sup>(</sup>f) 10% of cost for listed serviceable equipment

<sup>(</sup>g) Less than \$100

<sup>(</sup>h) Modules 3, 7, and 10 combined along with office cost

Table 7 - continued

Module	Equip- ment(b)	Identifi- cation(c)	Acqui- sition(d)	Instal- lation(e)	Debug- ging(e)	Mainte- nance(f)	Total
36	0	0	0	0	0	0	0
37	0	0	0	0	0	0	0
38	0	0	0	0	0	1.0	1
39	0	0 .	0	0	0	0	0
40	0	0	0	0	0.10	11	11
41	0.23	0.32	1.1	0	0	0	2
42	0	0	0	0	0	0	0
43	0.24	0.24	0.84	0	0	0	1
44	0	0	0	0	0	0	0
45	0.20	0.08	0.28	0	0.10	2.0	3
46	0	0	0	0	0	0.60	1
47	0	0	0	0	0	60	60
48	0	0	0	0	0.10	120	120
49	0	0	0	0	2.0	13	13
50	0	0	0	0	5.0	400	405
51	0	0	0	0	2.0	200	200
52	6.0	0.16	0.56	1.0	0.20	400	408
53	4.0	0.16	0.56	0.20	0.20	2.0	7
54	0	0	0	0	0.50	18	19
55	0	. 0	0	0	0.50	310	311
56	0	0	0	0	0	0	0
57	0	0	0	0	0.10	23	23
58	0.36	0.16	0.56	0	0.10	19	20
59	40	0.08	0.28	0.50	4.0	20	65
60	0	0	0	0	0	1.0	1
61	23	0.16	0.56	0	0.10	36	59
62	89	2.2	7.8	1.0	0.10	43	143
63	29	0.32	1.1	_0	0.10	14	45
	4,490	31	97	47	95	4,561	9,327
Phase 1	and Phase	2 (combined	) Totals:				
•.	15,867	87	301	252	190	9,122	25,830

TABLE 8 HIGH COST(a) EQUIPMENT ITEMS FOR AMTR FACILITY

Items	No. Required in a Facility Containing One of Each Module	Estimated Cost/Each (\$000)
Pyrolyser	1	300
GC (Electron Capture/FID)	2	30
GC-MS With Data Processing	1	150
HPLC	3	40
Electrophoresis Integrator and Recorder	1	30
Infrared Spectrophotometer	1	20
Atomic Absorption Spectrophotometer	2	20
Autoclave	1	50
Microscope	$\tilde{f 1}_{i}$	22
Electron Microscope	$ar{f 1}$	100
Liquid Scintillation Counter	4	20
Recording Chambers	4	20
Walk-in Freezer	2	20
Tunnel Type Cage Washer and Dryer	1	75
Centrifugal Analyzer With Pipettor and Computer	1	75
Storage Building	1	30
Microfiche System	1	22
Special Inhalation Chamber for Primate Behavioral Studies	2	25
Transformer	6	20
Diesel Generator	2	140
Parallel Switch Gear	2	20
Water Softener	2	25
Deionizer	ī	100
Waste Water Treatment System	ĺ	800
Centrifugal Chiller	4	200
Air Supply System	1	100
Air Exhaust System	1	100
Boiler, Primary	1	60
Boiler, Secondary	2	40
Telephone Communication System	1	35

<sup>(</sup>a) Equipment cost of \$20,000 or more

- 4. When considering inhalation chamber system design, utilize output information from USAMBRDL sponsored studies in progress that investigate inhalation toxicology methodology.
- 5. Carefully evaluate the protocol requirements spelled out in regulatory test standards for their equipment implications.
- 6. Consider establishing an equipment selection advisory committee for identifying major scientific items and providing technological guidance.

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# APPENDIX 1 EQUIPMENT LIST FORM

Function (\$500)** Operator Title (Euronam Inorthale Street) areallab   55 yrs.	Estimated   Capeciator Title   Capeciator Title				Equip	Equipment List	List	Comp	Complete by Area Laboratory No. Title	lory No.	,		
Function (\$000) Operator Title (\$100) Arrange (\$100) Operator Title (\$100) Operator Titl	Function (\$000) <sup>all</sup> Operator Title prevailed for the secondary >5 yrs.			Estimated		Capacity of Equipment		Expecter	1 Life	Size	<del> </del>		Special
	(a)	quipment Item	Function	(s)(000\$)	Operator Title	per unit of time)(b)		>5 yrs.>	11		-	_	equirements
	(£)								:				
	(£)												
	(a) Estimated average cost for item to include a cost range the average cost for item to include a cost range the average cost for item to include a cost range the average cost for item to include a cost range the average cost for item to include a cost range average.												
	(a) Estimated average cost for item to include a cost range the average.										<u> </u>		
	(a) Estimated average cost for item to include a cost range the average.  (b) Report throughput in samples per hour day if												
	(a) Estimated average. (b) Report Introughput in samples per hour or 8-hour day if												
	(a) Estimated average cost for item to include a cost range the average.  (b) Report throughput in samples per hour or 8-hour day if												
	(a) Estimated average cost for item to include a cost range the average.  (b) Report throughput in samples per hour or 8-hour day if												
	(a) Estimated average cost for item to include a cost range the average.  (b) Report throughput in samples per hour or 8-hour day if								<del> </del>				
	(a) Estimated average cost for item to include a cost range the average.  (b) Report throughput in samples per hour or 8-hour day if												
	(a) Estimated average cost for item to include a cost range the average.  (b) Report throughput in samples per hour or 8-hour day if												

# APPENDIX 2 INHALATION CHAMBER INVENTORY FORM

Inhalation	Chamber	Code	Number	

ı.	Name, address, phone number of organization contacted:
	ph. ( )
2.	Name of individual contacted and department:
3.	Assign code number to the chamber which is to be discussed and complete appropriate columns. Number should be in sequence with previous contacts.
	Model Name Number
	Vode1 Trme

Instructions for Inhalation Chamber Inventory

- 4. Complete survey form through those categories which apply, e.g., if chamber only, fill out chamber characteristics section.
- 5. Ask for specifications sheet. If available, have it sent to:

Mr. Greg Schiefer Life Systems, Inc 24755 Highpoint Road Cleveland, OH 44122

# INHALATION CHAMBER INVENTORY

	_	Code	for Diff	ering Cha	mber Type	s
	Chamber Characteristics					
1.	Package Chamber unit only Four or more additional equipment items required Less than four additional equipment items required Complete system with all required peripherals					
2.	Capacity (Volume, m <sup>3</sup> or 1) Cubic Meters, m Liters, 1 Weight, kg					
3.	Size (Dimensions, m) Length x Width x Height, m Diameter x Height, m Shape Cylindro-conical Cylindrical Square Ractangular Hexagonal Spherical					
	Animal Capacity (Approx. No. of) Mouse Rat Guinea Pig Hamster Rabbit Dog Primate Monkey Baboon Chimpanzee					
5.	Major Material of Construction Stainless Steel/Glass All Stainless Steel All Glass Aluminum Plastic (e.g., Lucite) Fiberglass					

continued-

Inhalation Chamber Inventory - continued

	<b>-</b> -	Code	for Diff	erine Cha	mber Types	
	Chamber Characteristics					
6.	Applicable to Acute Studies					
	Subchronic Studies	1	1	1		i
	Chronic Studies	j	1	1	1	•
	Carcinogenic Studies	}	3	. }	}	1
		1	}	1	\$	1
7.	Lab Area Associated with, ft <sup>2</sup> Chamber	Į			1	}
	Chamber and support equipment					1
8.	Types of Inhalation				Ì	
	Gases/Vapors	ł			}	1
	Aerosols	ł		}	}	l
	Particles	i				- 1
	Dust	į			İ	ľ
· <b>a</b> .	Chamber Internal Specifications	j			1	ſ
3.	Temperature C 2	1				}
	Chamber Capacity (m <sup>3</sup> )				1	
	Relative Humidity Z	ļ				
	Controlled	}				ł
	Normal-Range	l			}	ł
	Uncontrolled	ŀ			l	
	Normal-Range		•			
	Light Intensity - ft. candles	1				
	During Day	[				•
	During Night	- 1				
	Pressure, mmRg	j				}
	Normal-Range	1				
			1	ł		
10.	Electrical Power Supply, W (v)					
	AC					
	DC			[		
11.	Reliability Data			ł	i	
	Mean - Time - Between Failure, h			ļ.	ł	
	Mean - Time - to - Repair, h			ţ		
	Projected Equipment Lifetime, yr			Į		
	Project Operational Lifetime, yr			ļ		
12.	Maintenance			1		
	Level		ł	ł	}	
	Routine - Non-specialist		ł	ł	ł l	
	Special Personnel Required		Ì	1		i
	Expendables		1	1	1	
	Туре	i	ſ	1	[	į
	Replacement Frequency, mo.		í	}	<b>i</b>	
	Replacement Procedure, mo		]	J	}	]
			1	}	j	]
			·			

Inhalation Chamber Inventory - continued

Innalation Chambel Inventory - Continue	Code for Differing Chamber Types					
Chamber Characteristics						
and a ship time			1 '	1 1	1	
l3. Quantity of this type Produced	<b>(</b>	1	1	1 1	4	
rroduced In Use	1	1	1	1 7	1	
In use	t	}	1	1	1	
14. Operational Status	1		1	1	1	
Operating	1	ŀ	1	1	t '	
Ready to Operate	1	Ì	,	1	1	
Testing Stage	1	1	'	1	1	
Design Stage	1	]	,	1	1	
New Addition Coming Onstream	1	l	,	1 '	1	
15. Clean-out	1	1		1	1	
Internal System	1		1	,	•	
Pressurized	ł			,	1	
Drain	1		1	,	1	
Drying	}	1		,	1	
Special Sterilization Features	}	1	1	,	1	
External	}	ł		}	1	
Space Required	i	ł		1	1	
Connections	1	(			1	
Accessibility	1	}	1		1	
Time Required, min.	}	}		1	1	
Labor, h		1	1			
Between Cycling, h	1	1				
16. Cost	1	ļ			•	
Total Cost/Cycle	}	1	1	}	1	
Materials	1	1	}	1	1	
Personnel	l		1		1	
Power Input	1	1	}	1	İ	
Initial		}	1			
Maintenance	1	}		ì	1	
Operation at maximum rate/yr.	1		İ		1	
•			l		1	
17. Availability	Ş			1	1	
Construction lead-time required, mo.	<b>\</b>	1	1	}	1	
Development lead-time required, mo.	ł	1		Į	ł	
Air (In-Out)	1			1	}	
18. Input Air System		ł	1		1	
Filtration, % Removal			ì	1	l	
Flow Rate, m/sec (CFM)			l	1	İ	
Deserves kN/m² (DE1E)	1		1		1	
Test Agent Concentration, mg/m3 (ppm)	<b>)</b>	1	1	1	1	
Normal	Ì	ł	ł	ł	ł	
Range	1	1	}	1	Ì	
<u>-</u>	}	1	1	ł	1	
	Ì	1	}	}	~	

Inhalation Chamber Inventory - continued	Code for Differing Chamber Types					
Chamber Characteristics						
19. Exhaust Air Handling	•		1 1			
Efficiency of Venting	ļ					
Residual, mg/m³ (ppm)						
Special considerations for particulate/	í					
aerosols				i		
In Chamber						
On Animals and Cages		i				
Control/Monitor Functions				•		
20. Personnel Data:						
Number of Chamber Personnel to Operate				<b>\</b>		
Personnel Skill Level				[		
Work Period, h				j	}	
Maximum Weight Lifted, kg				ł	l	
Labor/Chamber Cycle				1		
21. Safety					ĺ	
Fail-safe Systems (Door Lockout)				1		
Sensors			1	Į į		
Warning Lights/Buzzer (Cycling and			Į	<b>!</b>	İ	
Sensor)			ţ		Ì	
Earthquake Proof Envelope		!	1	1	1	
Safety Level of Shock				1	ļ	
High Eazards - Particulate Carcinogens				1		
22. Performance Characteristics				1	j	
Test Agent Data			}	Ĭ	l	
Complete Cycling Time, min.				ì	}	
Time to Come up to Chamber concen-			<b>(</b>		[	
tration, min.			1	l	1	
Time to Get Down to Zero, min.			i		İ	
Test Agent Consumption Rate, 1 hr						
Instrumentation and Other Support Equipment					}	
23. Unique Features			)	j	1	
Walk-in					ļ	
Controllers	ı		}	1	1	
Temperature	ı			1	1	
Pressures			{		ľ	
Humidity		1	1	1	l	
Vibration		1		1	l	
Shock		!	i	}	ł	
Air Flow			ł	]	Į	
Rotating Drum					ļ	
Moveable		}	l	1	}	
Living Quarters			ļ	}	1	
Air Locks		}	ļ	}	]	
Wind Tunnel			1	1	1	
Automatic Atmosphere Sampling		1	<b>[</b>	1		
Multi-stress Capability		[		I	<b>§</b>	
Behavioral Observations			İ	ł	i	
Multi-animal Species Capability		L	L	<u> </u>	<u> </u>	

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